

REMARKS

I. INTRODUCTION

Claims 1 - 42 and 47 - 60 have been withdrawn from consideration. Claims 43 - 46 and 61 remain pending in this application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

II. THE REJECTIONS UNDER 35 U.S.C. § 102(b) SHOULD BE WITHDRAWN

Claims 43, 44 and 61 were rejected under 35 U.S.C. § 102(b) as anticipated by Yoon (U.S. Patent No. 5,797,888).

Claim 43 recites a medical device comprising “an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter” and “a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.*”

In contrast, Yoon purports to show a cannula for insertion through an anatomical cavity wall. (See Yoon, Abstract). The cannula 20 has a tubular body 22 with a seal 24 at a distal end thereof which is designed to open when a pusher 26 or an instrument 62 is thrust therethrough. (See id., col. 4, lines 25-30). The pusher 26 is “movable within the tubular body to open the seal.” (See id., col. 2, lines 16-18). The seal 24 includes four flaps (seal members) 28 biased toward a closed position “when no instrument is passed through the cannula.” (See id., col. 4,

lines 44-47). The flaps 28 open outwardly only when the pusher 26 or the instrument 62 is pushed therethrough. (See id., col. 7, lines 20-37). Specifically, Yoon states, “[p]usher 26 overcomes the closing force or bias of the seal members and spreads the seal members apart from one another.” (See id., col. 6, lines 60-62; Figs. 4, 6). The valve of Yoon is useful only to prevent fluid from passing therethrough as it seals around the pusher 26 or instrument 62 when such is passed therethrough and seals tight when no instrument extends therethrough.

The Examiner has stated that the slit of Yoon would inherently open due to differences in fluid pressure between the lumen and the ambient. (See 8/12/04 Office Action, ¶ 3). However, that reading of Yoon is directly contradictory to the teachings contained therein. Specifically, Yoon states that the seal 24 “can have any configuration to prevent fluid flow through the cannula prior to the introduction of instruments through the cannula, after the instruments are withdrawn from the cannula and/or while the instruments are in place.” (Id., col. 9, lines 54-57). The Examiner further stated that the slit in Yoon is configured to open inwardly when the ambient pressure exceeds the lumen pressure. (See 8/12/04 Office Action, ¶ 3). Again, that statement appears to contradict the disclosure in Yoon. Specifically, Yoon describes the use of a plurality of spring wires or stiffeners to maintain the seal in a closed position:

The seal members can be maintained in or biased to a closed, initial contracted position by a spine, shown by broken lines in Fig. 2 at 31, including a plurality of individual spring wires or stiffeners attached to the seal members. The spring wires can be disposed on the surface of the seal members or within the material forming the seal members. In the case of the seal members shown, the spring wires are disposed within the material of the seal and oriented along the lips to establish and/or maintain the configuration of the seal member in the closed position. (See Yoon, col. 4, line 62 - col. 5, line 4).

Use of the spring wires in the seal would prevent anything other than the pusher 26 or instrument 62 from opening the seal 24. It is respectfully submitted that there is no disclosure that would lead

one to conclude that the resilient force of the spring wires and other structures biasing the slits of Yoon closed would succumb to fluid pressure gradients and there is clearly no showing or suggestion that they would open under the influence of any fluid pressure gradients as are encountered in the anatomical environments to which medical devices are exposed.

Accordingly, the device of Yoon teaches away from the configuration claimed by the applicants. The applicants have disclosed a catheter that opens in response to a difference between a fluid pressure in the lumen and a fluid pressure external to the catheter. To accomplish the aspiration function, the compound slit is “able to flex into the internal lumen” when the lumen pressure is less than the environmental pressure. The seal 24 in Yoon never opens inwardly and only opens outwardly as a result of being physically pushed by the pusher 26 or the instrument 62. The seal 24 acts to prevent all fluid flow back into the cannula 20.

Thus, it is respectfully submitted that Yoon neither illustrates nor describes a medical device comprising “an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter” and “a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,*” as recited in claim 43. It is therefore respectfully submitted that claim 43 is not anticipated by Yoon and that this rejection should be withdrawn.

Because claims 44 and 61 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable.

III. THE REJECTIONS UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN

Claim 45 stands rejected as obvious over Yoon in view of Phelps et al. (U.S. Patent No. 6,419,659). The Examiner stated, in support of the rejection, that Yoon shows a device as claimed except for the element of a collar disposed at the distal end of the catheter, but that Phelps discloses a collar 46 disposed adjacent the catheter's distal-most end. The Examiner further stated that it would have been obvious for one of ordinary skill in the art to combine the above mentioned prior art and that "doing so would provide an attending physician with means for determining the location of the catheter by magnetic or electromagnetic means (Phelps column 4, lines 30-35)." (See 8/12/04 Office Action, ¶ 4).

It is respectfully submitted that claim 45 is allowable for the same reasons stated above in regard to claims 43, 44 and 61, and Phelps does not cure the noted defects.

Claim 46 stands rejected as obvious over Yoon in view of Desai (U.S. Patent No. 5,857,464). The Examiner stated, in support of the rejection, that Yoon shows a device as claimed except for the element of a tricuspid flap configuration, but that Desai discloses a valve 40 with three flaps 43. The Examiner further stated that it would have been obvious for one of ordinary skill in the art to combine the above mentioned prior art and that "it would be a simple matter of choosing a design for an end valve from existing designs known in the art, when each design would perform equally well." (See 8/12/04 Office Action, ¶ 5).

It is respectfully submitted that claim 46 is allowable for the same reasons stated above in regard to claims 43, 44 and 61, and Desai fails to cure the above-noted defects.

IV. CONCLUSION

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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